GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

UNSTARRED QUESTION NO:3020
ANSWERED ON:21.03.2017
Drug Literature
Singh Shri Ravneet

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether it is mandatory for drug manufacturers to provide drug literature along with their products and if so, the details thereof;
(b) whether the Government is aware of the fact that drug manufacturers have stopped providing drug literature along with their products and if so, the details thereof; and
(c) the details of the action taken/ being taken by the Government regarding the aforesaid issue?

Answer

MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS; MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH L. MANDAVIYA)

(a) to (c): As per Schedule Y of Drugs and Cosmetics Act, 1940 and Rules, 1945, manufacturer of new drug is required to submit product literature as a part of new drug application for marketing. The drafts of label and carton texts should comply with the provisions of Rules, 96 and 97. No incidence of not submitting product literature in above cases has been reported.

xxxxx